

**AllCare CCO - Prior Authorization Criteria Summary:****Criteria number: 092.1****Criteria title: desiccated thyroid**

Date of origin: 06/17/2019

**Classification: Drug Specific**

Date of Last Review: 06/17/2019

**Drug: desiccated thyroid (Armour Thyroid)**

Date of Next Review: 06/16/2021

## References:

- Oregon Health Authority, Department of Medical Assistance, OAR 410-120-0250 (3)
- Oregon Health Authority, Department of Medical Assistance, OAR 410-121-0147 (1)(h)
- Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria
- Williams, J., & Nieuwsma, J. (2018). Treatment of primary hypothyroidism in adults. David S Cooper, MD (Ed.), UpToDate. Retrieved June 17, 2019
- Jonklaas, Bianco, et al., Guidelines for the Treatment of Hypothyroidism: Prepared by the American Thyroid Association Task Force on Thyroid Hormone Replacement (2014) Thyroid 24(12): 1670-1751, 2014. <http://doi.org/10.1089/thy.2014.0028>

**FDA approved indication: N/A; Unapproved**

Purpose: To define the process for coverage of non-formulary desiccated thyroid

Clinical Rationale: Desiccated thyroid or thyroid extract refers to preparations that are derived from the thyroid gland of animals. These preparations were the primary therapy for hypothyroidism until the advent of synthetic T4 preparations in the 1960s. All commercially available prescription desiccated preparations are derived from pigs and are classified as an unapproved drug. For the vast majority of patients with hypothyroidism, combination T4-T3 therapy is not recommended. Desiccated thyroid extract has a T4-to-T3 ratio of 4:1, which is not physiologic (normal ratio of T4-to-T3 of 13:1 to 16:1). Although there is preliminary evidence from a short-duration study that some patients may prefer treatment using thyroid extracts, high-quality controlled long-term outcome data are lacking to document superiority of this treatment compared to levothyroxine therapy. Furthermore, there are potential safety concerns related to the use of thyroid extracts, such as the presence of supraphysiologic serum triiodothyronine levels and a paucity of long-term safety outcome data. American Thyroid Association (ATA) guidelines based on current studies do not support the use of combination T4-T3 products for thyroid hormone replacement, except in the rare subgroup of patients with a polymorphism in the type 2 deiodinase.

Normal replacement doses of Levothyroxine-liothyronine (porcine) thyroid hormone are not effective for weight loss, and large doses that would be required for reducing weight in euthyroid patients could lead to serious or even life-threatening toxicity. This is particularly dangerous when thyroid hormones are administered along with sympathetic amines that are also often used for weight loss.

Policy: Allcare CCO covers non-formulary desiccated thyroid for members with documentation of treatment failure (based on clinical lab values: i.e. TSH) with formulary agents [T4 (l-thyroxine) and/or T3 (liothyronine)] for members when prescribed by or in consultation with an endocrinologist.

1st Line Agent(s): levothyroxine

**Approval length: Up to 1 year****Approval Criteria for desiccated thyroid (Armour Thyroid):**

	<b>Met</b>	<b>Not Met</b>
Criteria #1: Is the request for a member established on desiccated thyroid	Go to Renewal section	Go to #2
Criteria #2: Is there documented diagnosis of hypothyroidism (requires TSH and T4 labs)	Go to #3	Deny
Criteria #3: Is the prescription written by (or in consultation with) and endocrinologist	Go to #4	Deny
Criteria #4: Is there documented treatment failure* with formulary thyroid agent [T4] (requires TSH, T3† and T4 labs) OR polymorphism in the type 2 deiodinase	Approve x1 year	Deny

**Renewal Criteria for desiccated thyroid (Armour Thyroid):**

	<b>Met</b>	<b>Not Met</b>
Renewal #1: Did the member meet initial PA criteria	Go to #3	Go to #2
Renewal #2: Is member new to plan and eligible for transition of care coverage	Approve for transition of care. Consider future denial	Go to #3

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Renewal #3: Is there documented treatment efficacy with non-formulary thyroid agent [T4] (requires TSH, T3† and T4 labs)

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Approve x1 year

Deny

Reviewed and approved by: Chief Medical Officer

Date: 06/18/2019